



## **Continuation Guidance – Budget Year Four**

### **Attachment D**

#### **Focus Area D: Laboratory Capacity – Chemical Agents**

##### **Background**

The purpose of this focus area is to develop nationwide laboratory capacity that provides rapid and effective analysis of clinical specimens (e.g., blood and urine) for chemical agents likely to be used in terrorism. These laboratory measurements will help guide emergency medical care, public health management of a chemical terrorism incident, and follow up of a chemical terrorism incident event by identifying the chemical agent(s) used, determining who has been exposed and how much exposure each person has had.

This focus area also addresses laboratory analyses of food specimens for chemical agents likely to be used in terrorism. The intent is to enable awardees to gain access to capabilities needed in their jurisdictions. This may be done by contracting for services with laboratories that possess the requisite capabilities, by sponsoring such capability development within collaborating organizations (e.g., food regulatory laboratories), and/or by developing the requisite capabilities directly within public health department laboratories. Technical assistance with respect to selection of analytic methods will be provided by FDA in consultation with CDC (see Appendix 1 for FDA contact information).

With respect to analysis of clinical specimens, the envisioned nationwide capability has three levels of laboratory capacity.

**Level-One Laboratories:** Awardees are eligible to receive funding to support a chemical terrorism laboratory coordinator and technical assistance/training to assist in management of laboratory assets and to properly collect and ship human blood and urine specimens in response to a chemical terrorism incident. Chemists and/or medical technologists will staff this function. Awards for Level-One laboratories will be limited to \$400,000 per awardee.

**Level-Two Laboratories:** Awardees that already have established or are in the process of establishing the capabilities of Level-One laboratories are eligible to receive financial support, technical assistance, equipment and training for analysis of human samples for Level-Two industrial chemicals, selected chemical threat agents (such as heavy metals, lewisite, and cyanide), or their metabolites. Development of Level-One and Level-Two capabilities may be concurrent activities. Level-Two laboratories will be equipped with state-of-the-art instrumentation including automated sample preparation equipment. These laboratories should be staffed with one Ph.D. chemist, or an individual with equivalent experience, and multiple laboratory support personnel.

To be eligible for Level-Two funding, the recipient must document a basic level of staff competency in analytical/clinical chemistry and laboratory quality control in measurements of low concentrations of chemicals or metabolites in clinical samples. Evidence of such competency would include a laboratory program in existence for at least one year involving the quantitative measurement of low levels of a toxic chemical, chemical metabolite, or biochemical



indicator of health status or disease risk in blood, urine, or other human specimens, or in environmental specimens (e.g. blood lead analysis program, EPA certification for chemical contaminant analyses of drinking water, or Clinical Laboratory Improvement Amendments (CLIA) certification for clinical chemistry measurements).

**Level Three Laboratories:** Laboratories will be funded to maintain capabilities of Level-Two laboratories, plus they will receive financial support, technical assistance, equipment and training for analysis of human samples for chemical threat agents that require a higher level of analytical expertise (e.g. tandem mass spectrometry). Such laboratories will be equipped with state-of-the-art instrumentation similar to the Level-Two laboratories but also will have more extensive automated sample preparation equipment and tandem mass spectrometers as necessary. These laboratories will be staffed with multiple Ph.D. chemists, or individuals with equivalent experience (M.S. with 5 years experience), and multiple support personnel. This will bring the total number of states funded at Level-Three to approximately 10. Acceptance into Level-Three will be contingent upon demonstrated analytical competency at Level-Two, including success in an accepted proficiency testing program for all Level-Two chemical agents. Level-Three laboratories will be chosen on the basis of the technical review, information provided in the application, program needs, national goals, and geographic location.

**CRITICAL CAPACITY #10 (Level-One Laboratories):** To develop and implement a jurisdiction-wide program that provides rapid and effective laboratory response for chemical terrorism by establishing competency in collection and transport of clinical specimens to laboratories capable of measuring chemical threat agents.

**RECIPIENT ACTIVITIES:**

**1. CRITICAL BENCHMARK #15 – APPLICABLE TO LEVEL-ONE**

**LABORATORIES:** Hire and train a chemical terrorism laboratory coordinator (chemist or medical technologist) and assistant coordinator to advise the laboratory director, the State Terrorism Coordinator and other public health and environmental health officials about chemical terrorism incidents and preparedness. These individuals are responsible for ensuring the proper collection, labeling, and shipment of blood, urine, and other clinical specimens required in response to known or suspected chemical terrorism incidents and for ensuring associated data and communication requirements are met.

2. Develop a component, incorporated within the comprehensive response plan, that directs how public health, food testing, environmental testing, and other laboratories within your jurisdiction will respond to a chemical terrorism incident. The plan must include (a) roles and responsibilities, (b) inter- and intra-jurisdictional surge capacity, (c) a description of how the plan integrates with other department-wide emergency response efforts, (d) protocols for the safe transport of specimens by air and ground, and (e) a mechanism for reporting laboratory data to public health officials, law enforcement agencies, and other chemical terrorism LRN laboratories. **(LINK WITH ALL OTHER FOCUS AREAS)**

3. Establish and document in the comprehensive response plan, relationships with local



members of HazMat teams, first responders, local, state, and federal law enforcement, and the Army National Guard (WMD-CST) to coordinate laboratory support for response to chemical terrorism with their response activities.

4. Join the chemical terrorism component of the Laboratory Response Network (LRN) and ensure that capacity exists (within the state, through partnerships with Level-Two and/or Level-Three laboratories in other states, or CDC) for validated testing of chemical agents in clinical specimens.
5. Enhance relationships with other chemical terrorism-related resources such as poison control centers, emergency medical personnel, medical toxicologists, food regulatory laboratories, schools of public health, and other partners with a view to ensuring that medical and public health officials have the benefit of at least preliminary chemical laboratory analyses in time to facilitate both the care of victims and the management of the incident. To this end, sponsor outreach efforts, professional conferences, and meetings.

**ENHANCED CAPACITY #7 (Level-Two laboratories):** In addition to establishing Level-One capacity, Level-Two Laboratories are to establish adequate and secure laboratory facilities, reagents, and equipment (e.g., ICP-MS, GC-MSD) to rapidly detect and measure in clinical specimens Level-Two chemical agents (such as cyanide-based compounds, heavy metals, and lewisites). Currently, CDC methods for Level-Two chemical agents use analytical techniques of inductively coupled plasma mass spectrometry and gas chromatography mass spectrometry. The list of Level-Two chemical agents may expand as better methods are developed. Tandem mass spectrometry methods are not required for Level-Two chemical agents. *Prerequisite: To be eligible for Level-Two funding, the recipient must document a basic level competency in analytical chemistry and laboratory quality control in measurements of low concentrations of chemicals in clinical samples. Evidence of such competency would include a laboratory program in existence for at least one year that includes the quantitative measurement of low levels of a chemical in blood, urine, or environmental specimens (e.g., blood lead analysis program, EPA certification for chemical contaminant analyses of drinking water, or CLIA certification for clinical chemistry measurements).*

#### RECIPIENT ACTIVITIES:

1. Develop or enhance plans and protocols that address: (a) clinical specimen transport and handling, (b) worker safety, (c) appropriate Bio-Safety Level (BSL) conditions for working with clinical specimens, (d) staffing and training of personnel, (e) quality control and assurance, (f) internal and external proficiency testing, (g) triage procedures for prioritizing intake and testing of specimens or samples before analysis, (h) secure storage of critical agents and samples of forensic value, and (i) appropriate levels of supplies and equipment needed to respond to chemical terrorism events. This should be documented in your comprehensive response plans.
2. Level-Two laboratories must, in collaboration with CDC, purchase equipment, hire and train



staff, implement analytical methods, participate in proficiency testing programs, and demonstrate competency in the analysis of Level-Two chemical agents or their metabolites in human specimens. Level-Two laboratories must achieve CLIA certification within 18 months of funding.

**3. CRITICAL BENCHMARK #16 – APPLICABLE TO LEVEL-TWO**

**LABORATORIES ONLY:** Participate in at least one exercise per year that specifically tests chemical terrorism laboratory readiness and capability to detect and identify at least one chemical-threat agent.

4. Use BSL-2 practices, as outlined in the CDC-NIH publication “Bio-safety in Microbiological and Biomedical Laboratories, 4<sup>th</sup> Edition” (BMBL), to process clinical specimens (e.g., blood and urine) -- see [www.cdc.gov/od/ohs](http://www.cdc.gov/od/ohs). CDC also recognizes the need that state laboratories have to safely handle unknown environmental samples. Laboratories are encouraged to participate with federal partners, the LRN, HAZMAT, first responders, and other state public health laboratories to develop and disseminate standardized methods, procedures, and protocols to safely triage, aliquot, transfer, ship, and store unknown clinical or environmental specimens potentially containing chemical, biological, radiological, or explosive agents. **(LINK WITH FOCUS AREA C)**
5. At a minimum, ensure that laboratory security is consistent with standards set forth in the Select Agent Rule or subsequent updates. Note that pursuant to 18 USC section 175b, as amended by section 817 of the USA PATRIOT Act of 2001, P.L. 107-56, aliens (other than aliens lawfully admitted to the United States for permanent residence) are prohibited from possessing select agents if they are nationals of countries about which the Secretary of State (pursuant to provisions of the Export Administration Act of 1979, the Foreign Assistance Act of 1981, or the Arms Export Control Act) has made an unrevoked determination that such countries have repeatedly provided support for acts of international terrorism.
6. Enhance and document Internet connectivity to enable rapid communication via the Internet for information and data transfer with chemical laboratories in the LRN. **(LINK WITH FOCUS AREA C & E)**

**ENHANCED CAPACITY #8 (Level-Three laboratories):** In addition to maintaining Level-One and Level-Two capacity, Level-Three laboratories are to establish adequate and secure laboratory facilities, reagents, and equipment (e.g., tandem mass spectrometer) to rapidly detect and measure in clinical specimens Level-Three chemical agents (such as nerve agents, mustards, mycotoxins, and selected toxic industrial chemicals). Level-Three laboratories will also provide surge capacity to CDC and serve as referral laboratories for Level-One and Level-Two laboratories. The five laboratories currently funded under Focus Area D (California, Michigan, New Mexico, New York and Virginia) are considered Level-Three laboratories. It is CDC’s intent in the future to add up to five additional laboratories at Level-Three. *Prerequisite: To be considered for acceptance into Level-Three, a laboratory must demonstrate analytical competency at Level-Two, including success in an accepted proficiency testing program for all*



*Level-Two chemical agents (e.g., heavy metals, lewisites, cyanide).*

RECIPIENT ACTIVITIES:

1. Level-Three laboratories must, in collaboration with CDC, purchase equipment, hire and train staff, implement analytical methods, participate in proficiency testing programs, and demonstrate competency in the analysis of Level-Three chemical agents or their metabolites in blood and urine.
2. **CRITICAL BENCHMARK #17 – APPLICABLE TO LEVEL-THREE LABORATORIES ONLY:** Participate in at least one exercise per year that specifically tests chemical terrorism laboratory readiness and capability to detect and identify at least two chemical-threat agents.
3. In collaboration with CDC and other Level-Three laboratories, participate in method development and validation studies.
4. Provide surge capacity to CDC and serve as a referral laboratory for Level-One and Level-Two laboratories.
5. Develop and implement a plan for 24/7 staff coverage in the event of a chemical terrorism emergency. Documentation of this plan should be provided to CDC to coordinate efforts.